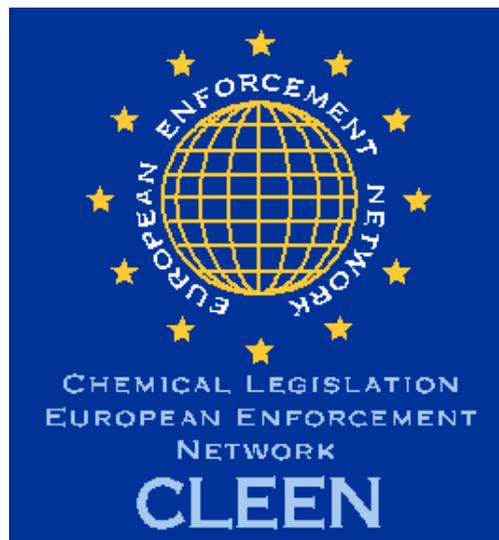


# **EurAzos**

## **FINAL REPORT**



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## SUMMARY OF THE PROJECT

EurAzos objective is to assess the compliance of textile and leather articles that might come into direct and prolonged contact with human skin or oral cavity, as well as of colouring agents placed or used on the European market with the legal provision on azodyes. The method used was spot-checking and the focus of the project was on dyed low priced articles e.g. imported from Asian countries.

The azodyes are dangerous to human health as they might release aromatic amines, which in direct and prolonged contact with the human skin or oral cavity are carcinogenic, mutagenic or toxic.

The difficulties for enforcement are caused by the fact that the presence of azocolourants in products cannot be detected unless laboratory analyses are performed, therefore it is difficult to establish a system for choosing certain products to be inspected.

Within CLEEN network, 9 countries decided to participate in the EuroAzos project: Austria, Denmark, Poland, the Netherlands, Belgium, Norway, Greece, Hungary and Estonia. The working group included Austria, Denmark and Poland and the project management was carried out by Austria. The working group developed the project manual, which was the base for preparing and carrying out the inspections during the project.

In total, 361 products were checked, 359 textile and leather articles and 2 colouring agents. In 9 cases violations were detected. The analysed samples showed good compliance of the companies, as only 2,5% of the samples were in violation. However, the method for inspections was, like in most market surveillance cases, spot checking. Products were chosen taking into consideration their risk, as much as it could have been predicted.

The results of the project might be affected by some laboratory difficulties: often it is difficult to achieve the same results in the same sample because of their heterogeneity; there is no clear procedure to choose the testing methods for textile composed of mixed natural and synthetic fibers; in some cases, there were found different concentrations of the forbidden aromatic amines in different laboratories for the same samples.

## I. INTRODUCTION

Azodyes or azocolourants are used in all parts of the world in different amounts and products. Such widely used chemicals are of great concern with regard to their potential dangerous properties.

Azodyes are synthetic dyes containing the azo group of two nitrogen atoms connecting aromatic ring compounds. They might release certain aromatic amines during the colouring process or during the use of products coloured with azocolourants.

Azocolourants are dangerous for human health because they can cause cancer, are toxic and are dangerous to human genes or reproduction if they come into direct and prolonged contact with human skin or oral cavity. One of the azocolourants is o-anisidine which is classified as category 2 carcinogen, category 3 mutagen and as toxic by inhalation, in contact with skin and if swallowed and it is included on the second priority list according to Existing Substances Regulation. The risk assessment of o-anisidine has identified the need for limiting the risk for consumers and at the workplace and the risk reduction strategy led to the inclusion of o-anisidine into the Restriction Directive.

Azodyes are widely used in the textile, printing, paper manufacturing, pharmaceutical and food industries and also in research laboratories.

According to the performed risk assessment, the general population may come into contact with the substance during the use of products coloured with pigments or dyes based on o-anisidine. From the usage of the substance the contact with printed packages and foils and with dyed textiles can be identified as the most important. These materials may contain free o-anisidine as residues or from degradation during the printing/dyeing process or during their use. In addition, especially in the case of dyes an unintentional release due to reductive cleavage after resorption may occur. The main exposure routes appear to be dermal (skin contact with printed packages, foils and dyed textiles and leather articles) and oral (young children sucking dyed textiles). A non-negligible risk was derived from exposure estimations concerning the dermal contact with dyed textiles and the oral uptake by young children sucking dyed textiles.

Workers may come into contact with o-anisidine during production, processing and during the formulation and use of o-anisidine based pigments. The main possible exposure routes appear to be via inhalation and dermal contact.

Although o-anisidine is a non-threshold carcinogen the risk for the different workplace operations concerning the uptake of the substance via inhalation can be regarded as negligible as the exposure levels are low and appropriate personal protective equipment is applied. The dermal exposure to o-anisidine is unquantifiable low for the most workplace operations at the manufacturers.

The Member States should take adequate preventive measures on the basis of the recommendation of the risk reduction strategy to effectively minimize the risk arising from the release of the substances from dyed textile and leather. Furthermore, the risk reduction strategy recommends ensuring the effectiveness of the measure taken by adequate monitoring programs.

Taking into consideration the above mentioned facts and a considerable number of violations reported into RAPEX system with regard to azodyes, Austria proposed a new European enforcement project to the CLEEN members during the 5<sup>th</sup> CLEEN Conference, The Hague, The Netherlands, fall 2004. This EurAzos project focused on textile and leather articles dyed with azocolourants and was performed primarily to control the limit values of dangerous substances released from textile and leather products, as well as from colouring agents and it concerned the enforcement of the Restriction Directive.

CLEEN is a voluntary network of chemical inspectorates in European Union, Norway and Switzerland that aims to coordinate the enforcement of EU chemical legislation by developing common strategies and tools for the inspectors in the member countries. It is basically a forum for information exchange and it performs enforcement projects as proposed by its members. As enforcement is the responsibility of the member states, the cooperation of the national chemical inspectorates in the European area is absolutely necessary in view of the rules of the single market and the EU-wide economy. The aim is to consolidate and intensify such co-operation so that compliance with chemical legislation can be improved for the protection of the human health and the environment.

## II. BACKGROUND

### II.1 Legislative background

Directive 2002/61/EC of the European Parliament and of the Council of 19 July 2002 which amended for the nineteenth time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (azocolourants) includes azocolourants as point 43 Annex I of the directive 76/769/EEC. The scope of the directive is to regulate azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines, in detectable concentrations, i.e. above 30 ppm in the finished articles or in dyed parts. These azodyes may not be used nor placed on the market in the textile and leather articles which may come into direct and prolonged contact with human skin or oral cavity, such as:

- clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags.
- footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck.
- textile or leather toys which include textile or leather garment.
- yarn and fabrics intended for use by the final consumer.

In January 2003 the European Commission issued the Directive 2003/3/EC (twelfth adaptation to technical progress of Council Directive 76/769/EEC) relating to restrictions on the marketing and use of “blue colourant” in textiles and leather articles.

This directive imposes restrictions on the “blue colorant” and the azodyes which are contained in the “List of Azodyes” (Annex 2) may not be placed on the market or used for colouring textile and leather articles as substances or constituents of preparations in concentrations higher than 0,1% by mass.

Azocolourants may split into aromatic amines. Among them, 22 species are reported to be carcinogenic and subject to control (Annex 1). According to the Directive 2003/3/EC azocolourants may not be used in textiles and leather that release at least one of the 22 listed aromatic amines.

Apart from the above mentioned Directive there is the Commission Directive 2004/21/EC of 24 February 2004 relating to restrictions on marketing and use of azocolourants (thirteenth adaptation to technical progress of Council Directive 76/769/EEC

which put “list of testing methods” according to which azocolourants should be analysed (Annex 3).

## **II.2 Goals of the project**

The main objectives of the EurAzos project was to assess the compliance of the textile and leather articles and colouring agents placed/used on the European market with the provisions regarding aromatic amines of the Restriction Directive 76/769/EEC (the 19<sup>th</sup> amendment and the 12th ATP) in order to minimise the risk for human health arising from the release of these substances from the mentioned products.

The following goals of this project were considered to be most important:

- reduction of risk to consumer from products which have direct and prolonged contact with human skin and oral cavity
- ensure risk reduction measures to be taken by provided adequate monitoring
- exchange of information and experience between Member States concerning product inspection
- strengthening of cooperation between inspectors, laboratories and enforcement authorities including interlaboratory studies concerning specific skills in analytical methods.

### **III. PROJECT DESCRIPTION**

As the EuroAzos project comprises inspection as well as sample analysis, the preparation of inspectors and laboratories are carried out in three phases, which according to the project manual are as follows:

1. Preparation phase
2. Inspection phase
3. Reporting phase.

#### **III.1. Preparation phase:**

The preparation phase was one of the tasks, which was carried out on a more joint level. In this phase the participation countries, the working group and the schedule of the project was decided on.

##### *III.1.1. Participating countries, working group and preparation of checklist*

The working group included Austria, Denmark and Poland. The project management was, from the beginning carried out by Austria which acted as focal point for all administrative tasks including coordination for elaboration of the inspection manual, drafting the time schedule and handing over the manual, as well as distribution of other joint/general information to the participating countries.

9 countries in the CLEEN network decided to participate in the EuroAzos project. The participating countries were Austria, Norway, Denmark, the Netherlands, Belgium, Poland, Greece, Hungary and Estonia (Annex 4).

The design of the project was built up using the necessary tools, which, besides the project manual and the training of the inspectors with regard to the relevant legislation, included a checklist (Annex 3). The checklist was prepared by the WG and complied with the legislation and the topics of the project in general.

### *III.1.2: Preparation of the participating countries*

Each country had to:

- Establish the necessary contacts for collaboration and initiate contacts between the parties involved (ministries, inspectorates and laboratories)
- Draw up a working plan taking into account the project manual
- Prepare their inspections: i.e. company visits
- Prepare sample analysis and enter into contracts with laboratories
- Prepare an inspection report custom made for the local inspectors.

### **III.2. Inspection phase:**

During this phase the inspections and the analysis of the samples were carried out:

#### *III. 2.1 Selection of products and product groups:*

The products covered by the legislation are:

1) Textile and leather articles which come into direct and prolonged contact with the human skin or oral activity, such as:

- Textile articles, e.g. underwear, pyjamas, shirts, tights, bedding, children's clothes, wristwatch straps, hairpieces, hats, nappies and other sanitary items, sleeping bags
- Leather articles: e.g. shoes, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck,
- Toys: e.g. toys intended for children up to three years of age (teething), which include textile or leather garments
- Yarn and fabrics intended for use by end customer

2) Agents for colouring textiles

### *III. 2.2 Selection of companies:*

Main emphasis was to be placed on companies selling imported dyed cheap articles (e.g. low-price article shops “1€ companies”, Asia shops) as well as textile colouring companies.

This was the intention when the project was planned. Some of the participating countries may have adapted the provision of the project manual, and established additional criteria for selecting the samples and the companies to be checked, after they considered the conditions of their local market. Some of the participating countries, among those Denmark and Austria, considered that significant problems might not only involve cheap products but rather that the problems were to be found in products coming from foreign countries, especially the Asian market. Other countries were not certain of the levels of agents for colouring used on their home markets and therefore decided to focus on that sector of the market.

### *III.2.3 Analyses of the samples*

All of the countries had to choose a laboratory which could carry out and use the testing methods specified in the directive. The testing methods are:

1. EN ISO/TS 17234:2003): Leather – Chemical tests – determination of certain azocolourants in dyed leathers
2. EN 14362-1:2003: Textile - Methods for the determination of certain aromatic amines derived from azocolourants - Part 1: Detection of the use of certain azocolourants accessible without extraction (EN 14362-1:2003)
3. EN 14362-2:2003: Textiles – Methods for determination of certain aromatic amines accessible by extracting the fibres. Part 2: Detection of the use of certain azocolourants accessible by extracting the fibres

Point 8.1 Preparation of test specimens of both standards EN 14262-1:2003 and EN 14362-2:2003, indicate the following:

Textile material is cut in an appropriate manner. For analysis 1,0 g of test material is weighted into the reaction vessel. In case of fabrics with various coloured patterns, the various colours have to be taken into account separately as far as possible. For commodities consisting of various textile qualities, specimens of the various qualities (in terms of fibre and/or colour) shall be analysed separately.

### **III.3. Reporting phase**

All results concerning the inspection of the companies, analysis and problems have been submitted by the Member States after the inspection phase was finished. The final report was prepared by the WG in spring 2007, and presented by the participating countries to the CLEEN group at the 8<sup>th</sup> CLEEN conference, 14-16 May 2007.

The participating countries submitted the results of the inspections performed in a summarized document and not the checklists filled in for each company inspected.

The parameters for considering the companies selected as well as the products are pretty well defined, and the working group found most of the information contained in the delivered reports acceptable, with regard to keeping the results comparable and sufficient.

Denmark, Austria, Poland, the Netherlands and Norway have given more detailed information to elucidate their preparatory phase, sample selection and project design. Belgium, Greece and Estonia have forwarded the most important topics of their design assessments. Hungarian results are not really included, as Hungarian test results did not include samples which were actually placed on the market. A summary of the most significant information from all the participating countries (including Hungary) descriptions is to be found below.

#### **Austria:**

In Austria the 9 regional Chemical Inspectorates within the federal states (Bundesländer) are responsible for enforcement of the chemical legislation. During the preparatory phase of the project, a training for the Austrian inspectors was performed in order to discuss the project in detail, presenting the manual, to develop a harmonized approach to the project at national level and to plan the control activities as well as the coordination with

the laboratories. With regard to the scope of the project, it was decided to inspect the main cheap chain stores of the Austrian market. The chain stores were divided up among the federal states to avoid the repetition of analyses of the same product in different states. In addition, one very expensive bed clothing shop from the region of Vienna was chosen to be checked, as a verification of the hypothesis that azodyes are most likely to be found in cheap products. The samples collected by the inspectors were sent for testing to the laboratory of the Federal Environmental Agency (Umweltbundesamt) in Vienna.

Examples of products checked are: T-shirts, textile slippers, shoes, gloves, bed sheets, towels. There was no specific criteria used to select the colour of the samples, the selected articles were of a wide range of colours, such as: red, orange, blue, green, yellow and multicoloured.

In total 39 samples were collected and 48 analysis were performed.

#### **Norway:**

The Norwegian Pollution Control Authority has focused on cheap products from low-price shops with direct import from Asia. They also bought some of the products on the Internet (web-stores).

Products have been chosen based on the following supplementary criteria:

- Bright colours
- Products in different shades of blue
- Products of natural fibres and leather

The product samples were carefully chosen from stores in the Oslo-area during June and August 2006. In total 40 products from 16 different stores were collected.

The products were numbered, photographed and send for analysis at Euofins in Oslo.

Norway also reported that they had carried out inspections for azodyes in textiles on three previous occasions:

- In 1998, 18 products were collected and tested for azocolourants (bedclothes, cuddly toys, and children's clothing which is in continuous contact with skin). Three of the products were not in compliance with the EU directive.
- In 2000, 17 products were collected and tested for azocolorants 8 items of children's clothing which is in continuous contact with skin, such as underwear). None of the products were non-compliant.
- In February 2006, 6 products were collected and tested for azocolorants (bedclothes and bath towels). None of the products were non-compliant.

### **Denmark:**

The Danish Environmental Protection Agency, Chemical Inspections section, has focused on relatively cheap products all intended for children from retail outlets. All retail outlets were part of a chain of stores, and the products were all made on the Asian market.

Products have been chosen based on the following supplementary criteria:

- Clear and strong colours
- Products which seemed to lose colours over time - not very colour fast
- Products of natural fibres and leather

The product samples were carefully chosen from stores in the area of Copenhagen during February and March 2006. Within the project, 40 products from 6 different stores were collected. The 6 different outlets comprised 2 toy shops, 1 supermarket, 1 clothes and handicraft shop - 1 only stocking products from India, 1 clothes store, 1 Euro (10 Danish crowns) shop.

All the products collected were intended for children clothes and toys. The products included Carnival suits, children's trousers, dresses, shoes, swimming tights, teething rings, socks, girls and boys blouses, finger gloves, sweat ribbons, toy cars, hair bands, girls belts, pillow cases, toy teddy bears, stuffed animals, finger dolls, textile dyes for children etc.

The products were numbered, photographed and sent for analysis to the Danish Laboratory Eurofins Environmental in Jutland.

Furthermore, Denmark analysed 19 products out of the 40 for content of azodyes (Annex 2). The products were sent to the Danish laboratory Eurofins Environmental and

though the laboratory forwarded to Bureau Veritas in Schwerin/Germany. The analyses for Azodyes called “Blue due or – navy Blue, were made according to index number 611-070-00-2. (The legislation states index number 611-070-00-2 with EC. No. 405-665-4 (Annex 3) )

In principle the legislation only obliges one to have “AzoDyes” analysed, but by mistake analysis on products which contained blue shades was carried out, only two of the products were dyes. None of the products showed infringement under a level of 100 ppm, and the presence of the regulated azodyes do not seem to be a problem in the analysed products and dyes.

### **Poland:**

Monitoring activities concerning compliance with EU law in Poland was conducted by the Trade Inspection, the State Sanitary Inspection and one independent institution: Institute of Dyes and Organic Products in Zgierz. The project concerned controlling the presence of prohibited azocolorants in shoes, textiles and leather articles.

Trade inspectors from Provincial Inspectorate of Trade Inspection in Łódź were responsible for the inspection activities including taking samples. The general procedure for taking samples was carried out in accordance with the Polish legal provisions governing the Trade Inspection, that is:

- act of 15 December 2000 on Trade Inspection (Dz. U. of 2001 No 4, item. 25 with amendments),
- regulation of the Prime Minister of 15 April 2002 concerning the specific way of taking and testing product samples by the organs of the Trade Inspection (Dz. U. z 2002 r., No 57, item 522)

Product samples were taken to discern whether the product complied with the quality and safety requirements described in other provisions or norms. The inspectors of the Trade Inspections are allowed to take samples free of charge.

Before starting the inspection phase, trade inspectors had received guidelines based on the Euroazos Manual as well as the experience of laboratory experts.

Detailed guidelines for taking samples were included in the instructions sent to the Voivodship Inspectorates of the Trade Inspection in Łódź (where they were used by inspectors collecting samples to be tested for content of aromatic amines).

The products were chosen using the following supplementary criteria:

- Dark and bright colours (blue, navy blue, black, brown, red, yellow, orange)
- Products containing cellulose fibres (cotton, mixture of polyesters and cotton)
- Products made of natural and synthetic fibres
- Products made of leather.

In addition Inspectors paid particular attention to products which had direct contact with human skin

The samples were delivered personally by the inspectors to the Trade Inspection Specialist Laboratory for Instrumental Analyses in Łódź in polyethylene bags, packed and sealed. At the laboratory the products were numbered, photographed and divided into symmetrical parts. One part of each product was sent to Institute of Dyes and Organic Products in Zgierz and second one was analysed at the Laboratory.

Trade inspectors have taken 30 samples from manufacturers, wholesalers and retailers. Samples were taken from the area of Łódź Province: 3 samples came from manufacturers, 13 from wholesalers and 14 from retailers. Among samples taken were: cotton T-shirts, nightdresses, bras, knickers, underpants and leather shoes, handbags, gloves and slippers. The majority of samples taken were of domestic origin but others came from Turkey, Italy and the Czech Republic.

The results were available at the end of February. The Chief Sanitary Inspectorate and The Trade Inspection as well as The Institute of Organic Compounds participated in the preparation of the final report.

### **Netherlands:**

In the Netherlands Directive 2002/16/EC has been implemented by the Warenwetbesluit azo-kleurstoffen (Decree on azo-dyes of 1998 under the Food and

Commodities Act.). The Food and Consumer Product Safety Authority (VWA) is the competent authority for market surveillance and enforcement of this regulation in The Netherlands.

Inspectors from the Food and Consumer Product Safety Authority carried out 100 inspections at army and navy dump stores and outdoor shops during 2006.

Supplementary criteria for the selection of the shops was based on the EurAzos project aim to target the cheap market segment. For the sake of efficiency, the VWA combined the CLEEN target with its own target – it was decided to inspect textiles where it was thought there was a white spot area: the so-called 'dump stores', which claim to be very cheap.

Because the number of samples from the dump stores was not sufficiently high, it was also decided to collect samples from a limited number of outdoor shops. Furthermore, the textile products from these kind of shops are also considered to be a 'niche' in the knowledge of the textile market in the Netherlands.

In total 99 samples were taken and analysed for azocolourants in accordance with EN 14362-1:2003. The analysis were performed by the Laboratory of the Food and Consumer Product Safety for Authority in accordance to EN 14362:2003 and the Standard Operation Procedure SIG01-ND428, VWA, Groningen of the Food and Consumer Product Safety Authority.

From the survey, it was found that 8 out of 99 samples contained one or more azocolourants.

### **Belgium:**

The Environment Inspection Section of the Federal Public Service Health, Food Chain Safety and Environment FOD carried out the inspections in Belgium. In this project, this governmental institution only has the competence to enforce the marketing of “navy blue” - Directive 2003/3/EC.

Belgium did not take samples, simply because no domestic lab was accredited for the specific analysis of “navy blue”. The inspection was therefore based on the information to be found on the labels of the colouring agents or based on the information contained in the SDS.

Belgium has many companies that are active in textile finishing. The Environment Inspection visited users of colouring agents as well as suppliers (importers and traders). In total 21 inspections were carried out of which 12 to the companies that are importers/traders of colouring agents and 9 to textile colouring companies.

### **Greece:**

The Agency of General Chemical State ( gzk-environment?) carried out the inspection in Greece. Following consultation with other Public Services which were also involved in monitoring programmes relation to the implementation of the azodyes Directives they decided that the supplementary criteria for the project should focus mostly on imported items. The programme lasted for 1 year, from March 2006 to March 2007. 98 products (textile and leather samples) of which 75 products was imported and 23 was from the domestic market were sampled and analysed in the laboratory in the Agency (General Chemical State laboratory) during that period.

Among the analysed products, 2 were not in compliance with the provision of the Directive. These products were imported from China and India.

### **Estonia:**

The preparation phase in Estonia was carried out during the first quarter of 2006. During this phase the manual and checklist were translated into Estonian and inspectors were trained. The agreement for testing with a laboratory in Austria was entered into as well.

During the inspection phase in the second quarter, the companies to be inspected were selected. / companies which import goods from third countries (mostly China) and sell the products at a low cost/low price level. The inspectors sampled 15 products all together that included coloured textile clothing (shirts, socks, scarfs, underpants, gloves, boxers etc), textile and leather footwear (slippers), textile handbags and toy – 13 of the articles were intended for

children and 2 textile articles (underpants and shirts) for adults. The samples were sent to the laboratory by mail/post.

The results of the analysis, carried out in accordance with CEN ISO/TS 17234, EN 14362-1 and EN 14362-2 gave negative results and the regulated aromatic amines were not detected.

### **Hungary:**

During 2006 and 2007, the Hungarian laboratory Chemical, Food Product and Environment Protection Section analysed 117 products regarding the release of certain aromatic amines derived from azodyes. Although most of the samples were analysed according to the methods required by the Restriction Directive, the results couldn't be taken into account for the present project, as the samples were tested at the request of the companies, before intending to place the products on the market. The products to be tested were not selected during inspections and no information is available regarding the placing on the market of the products detected positive.

Hungarian results are only mentioned in the present report and are not considered for the overall results of the EurAzos project.

## **IV. THE COMPILATION OF THE DATA AND RESULTS**

### **IV.1. Introduction**

The presence of azocolourants in products (articles or colouring agents) cannot be detected unless laboratory analyses are performed, therefore it is difficult to establish a system for choosing certain products to be inspected. The criteria used to select both the companies and the samples to be inspected were determined in the project manual. The participating countries planned and coordinated the Inspection phase of the project at the national level.

It was not possible to establish criteria (such as colour, material, type of product etc.) that could be used to indicate products that should be suspected of violating legal requirements relating to the presence of azocolourants. Therefore, neither the qualifications nor the experience of the inspectors who took part in EurAzos project can contribute toward establishing such criteria for the detection of non-compliance.

Therefore, it is necessary to perform analyses for detecting violations concerning restrictions of azocolourants and the procedure was as follows: carrying out inspections to the selected companies, collection of samples and submission of the samples to the laboratory.

Different problems might arise when screening the European market and the number of the companies and samples checked in each country might give different overview of the presence on the local market of the forbidden azocolourants in leather and textile articles as well as in the colouring agents.

The most challenging part of the project turned out to be the performance of the analysis, thus the laboratories involved played the most significant role.

The results after the collection and compilation of the data submitted by the participating countries are described in the next sections of this chapter.

### **IV.2. Inspected companies**

The companies planned to be inspected were “the companies selling imported dyed cheap articles and textile colouring companies”.

Additionally, the participating countries decided which economic agents would be inspected also depending on the local conditions or on other criteria they considered relevant. This way

each country contributed to the project, following the same baseline, but adding information from a different sector of the market. An overview over the inspected companies in the different countries is presented:

**Austria:**

It was decided to inspect big chains of stores that are selling cheap products, but also a very expensive shop specialized in selling bed clothing, just to have examples of expensive products and check if there is a connection between the price and the use of forbidden azocolourants.

**- Denmark:**

The products were selected from: 2 toy shops, 1 supermarket, 1 clothes and handicraft shop, only stocking products from India, 1 clothes store and 1 £ (10 Danish Crowns) shop and were mainly manufactured in India, Japan and China.

**- Poland:**

The samples were collected from producers, wholesalers and retailers and most samples were manufactured in Poland, except a few originated in Turkey, Italy and Czech Republic.

**- Norway:**

The inspections were focused on cheap products from low-price stores or shops with direct import from Asia. Some of the products were purchased from electronic shops via the internet.

**- Netherlands:**

Most of the samples were collected from army and navy dump stores and a smaller number of samples were collected from out door shops.

**- Belgium:**

Inspections were performed at textile colouring companies as well as at traders and importers of colouring agents.

**- Greece:**

From the total of 98 samples tested during the project, 75 were imported (e.g. China, India) and 23 from the internal market.

**- Estonia:**

There were selected 7 companies that import cheap products mostly from China.

**- Hungary:**

The samples were tested at the request of the importers, before placing the goods on the market, thus the results are only mentioned in the present report and are not considered for the overall results.

### **IV.3. Criteria for Selection of samples**

The main focus with regard to selecting and analysing the samples were the products covered by the Restriction Directive, such as textile and leather articles which come into direct and prolonged contact with human skin or oral cavity, as well as agents for colouring textile should be analysed.

Besides these criteria, the participating countries established others that helped them to narrow the field they would check. For example:

**Denmark:**

The criteria for choosing a product was limited to choosing products of clear strong colours which furthermore, on the basis of a visual assessment, seemed water soluble.

**Belgium:**

It was decided to verify colouring agents, according to the information provided in the SDSs or on the labels, with a special focus on blue pigments.

**-Norway:**

The products selected were for children use and characterized by having bright colours or different shades of blue and composed by natural and synthetic fibres or leather.

#### IV.4. Number of Products Analysed

In total 361 products were analysed.

- articles: 359
  - textile: 337
  - leather: 17
  - textile and leather: 5
- colouring agents: 2

Table nr. 1 presents the number of products tested in each participating country.

Table nr. 1: The number of products analysed

<b>Country</b>	<b>Total No. of Products</b>	<b>No. of Textile Articles</b>	<b>No. of Leather Articles</b>	<b>No. of Leather and Textile articles</b>	<b>No. of Colouring Agents</b>
<b>Austria</b>	39	36	0	3	0
<b>Denmark</b>	40	35	3	0	2
<b>Estonia</b>	15	13	1	1	0
<b>Greece</b>	98	96	1	1	0
<b>Norway</b>	40	38	2	0	0
<b>Poland</b>	30	20	10	0	0
<b>Netherlands</b>	99	99	0	0	0
<b>TOTAL</b>	361	337	17	5	2

The number of each type of product was determined mainly by studying the testing methods reported to be used for each method and in few cases compared with photos, where available.

In addition, outside the scope of the project, Hungary analysed 113 products, from which 106 were textile articles and 7 leather articles.

Although chances are small, one should notice that it is possible that the same product or more similar products from the same producer were inspected in more than one country or in more than one region within the same country.

#### **IV.5. Type of products tested**

Most countries checked only leather and textile articles, except Denmark which tested 2 colouring agents (acrylic paint and fabric paint – both for children play).

Belgium checked colouring agents from 9 textile colouring companies and 12 traders/importers. No laboratory analyses were performed.

The articles analysed were made of leather and natural or synthetic fibres, such as cotton, polyester, elastane, polyamide, nylon, wool, or mixtures of the mentioned materials, which sometimes led to more than one analysis for the same product. In one case, the sample was reported to be made of paper (hat), but it was decided to add this sample to the total number of products tested within the project, as during a second analyses it was difficult to recognize the material and it is likely that people wear this kind of product.

A wide range of products were analysed during the project, such as:

- textile articles (e.g. tops, T-shirts, towels, trousers, shawls, bed sheets, carnival suits, dresses, handbags, swimming tights, teething rings, socks, blouses, sweat ribbons, hair bands, pillow cases, teddy bears, stuffed animals, finger dolls, slippers, underwear, scarves, hats, nightdresses, blankets)
- leather articles (e.g. shoes, boots, belts, slippers)
- textile and leather articles (e.g. gloves, shoes, toys)
- colouring agents (tubes of paint)

#### **IV.6. Colour of the samples**

The samples selected for laboratory analysis covered a wide range of colours and shades: yellow, red, blue, pink, orange, purple, green, black, turquoise, beige, grey etc and combinations for different colours (multicoloured materials). The intensity of the colours varied from very light to very strong colours.

Some efforts have been done to find out a possible correlation between the certain colours and the content of forbidden aromatic amines.

During the preparation phase, Denmark used the available sources of information on azodyes: literature references, Google search and Eurofins laboratory, which carried out the analysis for the Danish samples. The conclusion was that azodyes containing the 22 regulated amines are to be found in almost the whole colour spectrum.

Poland found a web based information that “azodyes are usually red, brown, or yellow and make up about half the dyes produced”. The statement was made in the electronic version of the Hutchinson encyclopaedia and the link is provided below: <http://www.tiscali.co.uk/reference/encyclopaedia/hutchinson/m0024365.html>. However, it is mentioned that the colours are “usually” red, brown (which is a derived colour from red) and yellow and it was considered that the information was not reliable enough or at least not sufficient. Therefore, in Poland it was decided to analyse dark and bright colours from a wider spectrum, such as navy blue, black, red, yellow, orange, blue.

#### **IV.7. Testing Methods**

Samples of textile and leather articles, as well as of colouring agents have to be analysed using the 3 methods mentioned in paragraph III.2.3. During the laboratory testing the concentration of aromatic amines is measured and not the azodyes themselves.

The project focused on the methods mentioned above and only samples tested with these methods were considered for the final report. Additional to the European testing methods, outside the scope of the EurAzos, Denmark analysed 19 samples for content of “Azodyes”. The blue dye analyse was carried out with the following analytical principle: Azodye/”navy blue” separates a primary aromatic amine during sample preparation. At presence above 100 mg/kg (analysed at GC/MS) the results is verified quantitatively at HPLC-MS. I.e. the results is given as > 100 mg/kg. LOD is 100 mg/kg.

Each of the mentioned methods is designated to a certain category or categories of materials. There were situations when the same product was analysed with more than one method as the sample composed from few combined materials (e.g. leather with cotton or different types of textiles).

The standards used for testing the textile articles mention that 1,0g of test material is necessary to perform the analyses, but in practice at least 30g of material is necessary in order to obtain the 1,0g sample.

The sampling is very important as it must be representative for the product tested and its heterogeneity and reduced size of the sample might influence the result.

During the project 285 samples were tested with EN 14362-1:2003, 72 with EN 14362-2:2003 and 22 with CEN ISO/TS 17234:2003. In total, 379 tests were performed for 361 products. Additionally, 7 analyses were performed for crosschecking the positive results reported for 6 samples (5 from the Netherlands and 1 from Poland). One sample had to be tested twice due to the mixture of two colours (red and golden) on the textile that lead to different results of the analyses.

One should take into account that the total number of products verified was 382, but for 21 products there were no tests carried out.

In the Table nr. 2 a general overview of the European methods used in each country to test the samples is given.

Table nr. 2: Testing methods

<b>Country</b>	<b>Total no. of analysis performed</b>	<b>EN 14362-1:2003</b>	<b>EN 14362-2:2003</b>	<b>CEN ISO/TS 17234:2003</b>
<b>Austria</b>	48	36	9	3
<b>Denmark</b>	40	27	10	3
<b>Estonia</b>	17	10	5	2
<b>Greece</b>	105	74	29	2
<b>Norway</b>	40	19	19	2
<b>Poland</b>	30	20	0	10
<b>Netherlands</b>	99	99	0	0
<b>TOTAL 1</b>	<b>379</b>	<b>285</b>	<b>72</b>	<b>22</b>
<b>Cross-checking</b>	7	7	0	0
<b>TOTAL 2</b>	<b>386</b>	<b>285</b>	<b>72</b>	<b>22</b>

In the last 2 years, Hungary, outside the project, analysed 117 samples for azodyes:

- EN 14362-1:2003: 81
- EN 14362-2:2003: 22
- ISO/TS 17234:2005: 7
- EN 71-11:2006 (for toys): 7

#### IV.8. Results of the analysis

Positive results were reported in 9 cases (2,49 %), out of the of 361 products verified during the project. The positive samples were reported by the Netherlands (6), Poland (1) and Greece (2).

##### The Netherlands:

From the 99 samples collected, 8 contained one or more azocolourants and after reduction of the colourants, in 6 samples aromatic amines were found in concentrations above 30 mg/kg. In these samples the following aromatic amines were found: benzidine, 4-aminodiphenyl, o-toluidine, toluene 2,4 diamine and o-dianisidine , concentrations varied from 3 mg/kg 4-aminodiphenyl to 552 mg/kg benzidine. The concentrations of benzidine in samples 3 exceeded the 30 mg/kg limit more than tenfold.

The summary of the samples and measures imposed are foreseen in Table 3:

Table 3: Positive samples in the Neatherlands

Sample #	Garment	Aromatic amine (cas #)	Concentration (mg/kg)	Colour	Fibre-composition	Mandatory measures
1	shawl	benzidine (92-87-5) 4-aminodiphenyl (92-67-1)	419 49	black	100% viscose	Administrative fine
2	shawl	benzidine (92-87-5) 4-aminodiphenyl (92-67-1)	526 68	black	100% viscose	Administrative fine
3	shawl	benzidine (92-87-5) 4-aminodiphenyl (92-67-1)	552 40	red	100% viscose	Administrative fine
4	shawl	o-toluidine (95-53-4)	82	red	n.k.	Administrative fine
5	pants	toluene 2,4 diamine(95-80-7) benzidine (92-87-5)	> 30 6	red/grey	n.k.	No mandatory measures
6	hat	4-aminodiphenyl (92-67-1) benzidine (92-87-5) o-dianisidine (119-90-4)	3 25 31	black	paper	No mandatory measures
7	lady top	o-anisidine (90-04-0)	30	green	100% cotton	No mandatory measures
8	lady top	o-anisidine (90-04-0)	9	green	100% cotton	No mandatory measures

**Poland:**

From the 30 samples collected, the test results showed that only one product contained more than 30 ppm of the forbidden aromatic amines. Furthermore, this prohibited level was very high as the standard was exceeded more than 20 times.

The concentration of aromatic amines was:

- 630 [ppm] according to the Specialist Laboratory for Instrumental Analyses, Łódź
- 550 [ppm] according to the Laboratory of Product, Process and Environmental Research of Institute of Dyes and Organic Products, Zgierz

The forbidden aromatic amine was 3,3'-dimethoxybenzidine.

**Greece:**

In 2 cases out of the 105 samples collected, the analysed products contained more than 30 ppm of the forbidden aromatic amines and these were imported from China and India.

**Crosschecking:**

Taking into account that only a very small number of the tests revealed the presence of forbidden amines in concentrations above the accepted limit, Austria, in its quality of project leader, wanted to make sure that the reported positive samples are actually positive and offered to the Netherlands, Greece and Poland to cross check the results of their analyses with the laboratory of the Federal Environmental Agency in Austria (Umweltbundesamt), free of charge. The Netherlands sent 6 samples for being retested in Austria, from which 5 were analyses and Poland 1. The results indicated that:

- the sample from Poland was positive, but the concentration of aromatic amines was 10 ppm, below the threshold value (30 ppm)
- the samples from the Netherlands were all positive, above the threshold value, with concentrations between 48 – 309 ppm, on average about half the concentration reported by the Netherlands.

It was not possible for Greece to send their positive samples to Umweltbundesamt Austria, due to internal procedures.

Further consideration was given in the case of the Polish sample, as the result of the cross-checking varied very much and the concentration reported by the laboratories was in one case below the threshold value and in the other case much above the threshold value. The

laboratories then came into direct contact and sampling issues were brought into attention. The sample collected from the store was a T-shirt and different parts of it were analysed in Polish laboratories and in the laboratory of the Federal Environmental Agency in Austria (Umweltbundesamt). The conclusion was that the results could not be compared and the cross-checking was not relevant in this case.

General conclusion:

Cross-checking only makes sense if the samples analysed are identical and homogenous.

#### **IV.9. Sanctions and measures imposed**

##### **The Netherlands:**

There were imposed 4 administrative fines to the trading companies and in 2 cases no mandatory measure could be taken as the concentration of the forbidden aromatic amines couldn't be determined exactly. Because it was established that there were no European trading channel involved, no RAPEX notification was submitted.

##### **Poland:**

For that didn't comply with the legal requirements, it was prepared a file that was passed to the Office of Competition and Consumer Protection to take appropriate administrative measures. The case is in progress.

##### **Greece:**

It was forbidden to continue to place on the market the 2 products found not compliant with the requirements of the legislation.

## V. CONCLUSIONS AND RECOMMENDATIONS

### V.1. Conclusions

The presence of azocolourants in products (articles or colouring agents) cannot be detected unless laboratory analyses are performed, therefore it is difficult to establish a system for choosing certain products to be inspected. The criteria used to select both the companies and the samples to be inspected were determined in the project manual. The participating countries planned and coordinated the Inspection phase of the project at the national level.

It is difficult to establish criteria for selecting the samples to be analysed. The participants to the project tried to establish correlations between certain criteria and violations e.g. colours. The conclusion was that colours are not indicators for the content of the 22 forbidden aromatic amines.

The analysed samples showed good compliance of the companies, as only 2,5% of the samples were in violation. However, the method for inspections was, like in most market surveillance cases, spot checking. Products were chosen taking into consideration their risk, as much as it could have been predicted.

The results of the project might be affected by some laboratory difficulties: often it is difficult to achieve the same results in the same sample because of their heterogeneity (with regard to materials and dyes used); there is no clear procedure to choose the testing methods for textile composed of mixed natural and synthetic fibers; in some cases, there were found different concentrations of the forbidden aromatic amines in different laboratories for the same samples.

The strategy used during the project was to focus on cheap products, especially on those imported from East Asian countries. More expensive products might also be interesting for enforcement in future, bearing in mind that manufacturing is often located in several countries where the production is cheaper.

The industry is responsible for their products, for providing information related to the composition of their products and for demonstrating their compliance with the legal

provisions. In case the companies cannot provide such information, they should pay for analyzing the samples taken by the inspectors. However, this is not possible in all European countries.

## **V.2 . Recommendations**

### *V.2.1. To the European Commission and to the Forum*

- to elaborate enforcement strategies for articles
- to support the cooperation between the Member States e.g. cooperation between accredited laboratories, cooperation between inspectors
- to develop testing methods for articles with mixed fibers, natural and synthetic
- to speed-up the procedure for the publication of the RAPEX notifications

### *V.2.2. To the EU Member States/EEA countries*

- to continue the enforcement activities for checking the compliance of the products on the market with the provisions of the Annex XVII of REACH Regulation on azodyes
- to cross-check some of their samples between different accredited laboratories located in different Member States – “ring cross-checking” and use identical samples for this purpose
- to follow the RAPEX notifications and take action immediately (often the products notified through RAPEX are not present in shops anymore when the inspectors arrive)
- to inspect also expensive articles or imported colouring agents
- to ask the industry to pay for analyses if they are not able to prove their compliance

### *V.2.3. To the Industry*

- to ask their providers for the information on the composition of the products they purchase, including the used dyes
- to introduce quality management in the companies also with regard to substances that they are using
- to improve communication within professional associations (legislation, knowledge on products on the market that violates the legal provisions)

## Annex 1:

### LIST OF AROMATIC AMINES

	CAS No	Index No	EC No	Substance	Classification
1	92-67-1	612-072-00-6	202-177-1	biphenyl-4-ylamine 4-amino biphenyl xenylamine	Carc. Cat. 1; R45 Xn; R22
2	92-87-5	612-042-00-2	202-199-1	benzidine	Carc. Cat. 1; R45 Xn; R22 N; R50-53
3	95-69-2	612-196-00-0	202-441-6	4-chloro-o-toluidine	Carc. Cat. 2; R45 Muta. Cat. 3; R68 T; R23/24/25 N; R50-53
4	91-59-8	612-022-00-3	202-080-4	2-naphthylamine	Carc. Cat. 1; R45 Xn; R22 N; R51-53
5	97-56-3	611-006-00-3	202-591-2	o-aminoazotoluene 4-amino-2',3'- dimethylazobenzene 4-o-tolylazo-o-toluidine	Carc. Cat. 2; R45 R43
6	99-55-8	612-210-00-5	202-765-8	5-nitro-o-toluidine	Carc. Cat. 3; R40 T; R23/24/25 R52-53
7	106-47-8	612-137-00-9	203-401-0	4-chloroaniline	Carc. Cat. 2; R45 T; R23/24/25 R43 N; R50-53
8	615-05-4	612-200-00-0	210-406-1	4-methoxy-m-phenylenediamine	Carc. Cat. 2; R45 Muta. Cat. 3; R68 Xn; R22 N; R51-53
9	101-77-9	612-051-00-1	202-974-4	4,4'-methylenedianiline 4,4'-diaminodiphenylmethane	Carc. Cat. 2; R45 Muta. Cat. 3; R68 T; R39/23/24/25 Xn; R48/20/21/22 R43 N; R51-53
10	91-94-1	612-068-00-4	202-109-0	3,3'-dichlorobenzidine 3,3'-dichloro biphenyl-4,4'-ylene diamine	Carc. Cat. 2; R45 Xn; R21 R43 N; R50-53
11	119-90-4	612-036-00-X	204-355-4	3,3'-dimethoxybenzidine o-dianisidine	Carc. Cat. 2; R45 Xn; R22
12	119-93-7	612-041-00-7	204-358-0	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine	Carc. Cat. 2; R45 Xn; R22 N; R51-53

13	838-88-0	612-085-00-7	212-658-8	4,4'-methylenedi-o-toluidine	Carc. Cat. 2; R45 Xn; R22 R43 N; R50-53
14	120-71-8	612-209-00-X	204-419-1	6-methoxy-m-toluidine p-cresidine	Carc. Cat. 2; R45 Xn; R22
15	101-14-4	612-078-00-9	202-918-9	4,4'-methylene-bis(2-chloro aniline) 2,2'-dichloro-4,4'-methylene dianilin	Carc. Cat. 2; R45 Xn; R22 N; R50-53
16	101-80-4	612-199-00-7	202-977-0	4,4'-oxydianiline	Carc. Cat. 2; R45 Muta. Cat. 2; R46 Repr. Cat. 3; R62 T; R23/24/25 N; R51-53
17	139-65-1	612-198-00-1	205-370-9	4,4'-thiodianiline	Carc. Cat. 2; R45 Xn; R22 N; R51-53
18	95-53-4	612-091-00-X	202-429-0	o-toluidine 2-aminotoluene	Carc. Cat. 2; R45 T; R23/25 Xi; R36 N; R50
19	95-80-7	612-099-00-3	202-453-1	4-methyl-m-phenylenediamine	Carc. Cat. 2 ; R45 T ; R25 Xn ; R21 Xi ; R36 R43 N; R51-53
20	137-17-7	612-197-00-6	205-282-0	2,4,5-trimethylaniline	Carc. Cat. 2; R45 T; R23/24/25 N; R51-53
21	90-04-0	612-035-00-4	201-963-1	o-anisidine 2-methoxyaniline	Carc. Cat. 2; R45 Muta Cat. 3; R68 T; R23/24/25
22	60-09-3	611-008-00-4	200-453-6	4-amino azobenzene	Carc. Cat. 2; R45 N; R50-53

## Annex 2:

### LIST OF AZODYES

CAS No	Index No	EC No	Substance	Classification
Not allocated	611-070-00-2	405-665-4	A mixture of: disodium(6-(4-anisi-dino)- 3-sulfonato-2-(3,5-dinitro-2-oxido-phenyl azo)-1-naphtholato) (1-(5-chloro-2-oxido phenylazo)- 2-naphtholato) chromate(1-); trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxido-phenylazo)-1-naphtholato) chromate(1-)'	R43 N; R50-53

## Annex 3:

### CHECKLIST

#### PART 1:

<b>1. General information</b>	
Country	
Date of inspection	
Inspector	
<b>2. Company data</b>	
Name	
Size (number of employees)	
Category (producer, importer, trading/retail comp.,...)	
Knowledge in Company If Yes	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> external <input type="radio"/> internal
<b>3. Company data/Optional</b>	
Member professional organisation	<input type="radio"/> Yes <input type="radio"/> No
Member environmental certification (e.g. EMAS, ISO 14000, internal system)	
Supplier (international company/local/domestic)	
Clients (multinational company/retailer/consumer)	
Regulated articles (knowledge, are duties fulfilled,...?)	

## PART 2:

<b>4. Product</b>	
Name (trade name)	
Country of origin	
Scope of azodyes	<ul style="list-style-type: none"><li>○ Azodyes in textile/leather articles</li><li>○ Azodyes in colouring agents</li></ul>
<b><u>Fill in only in case of an article coloured with azocolourants:</u></b>	
Kind of product (towel, gloves, toy,...)	
Description of product (colour, textile or leather)	
<b>5. Analysis</b>	
Laboratory (name of lab, ref. to the accreditation, ...)	
<b><u>Sample 1:</u></b>	
Identification: description of piece of coloured product: part of the product, e.g. sole of shoe, garment of doll or doll itself, colour, textile or leather	
Test method	<ul style="list-style-type: none"><li>○ CEN ISO/TS 17234:2003 (leather)</li><li>○ EN 14362-1:2003 (textiles, without extraction)</li><li>○ EN 14362-2:2003 (textiles, extracting the fibres)</li></ul>
Result	<p><u>Concentration of aromatic amines <sup>(1)</sup>:</u></p> <ul style="list-style-type: none"><li>○ No detectable concentration of aromatic amines above the detection limit</li><li>○ _____ [ppm] (sum of aromatic amines) Name of amine(s):</li></ul> <p><u>or</u></p> <p><u>Concentration of azodyes <sup>(2)</sup>:</u></p> <ul style="list-style-type: none"><li>○ &lt; 0.1 % by mass</li><li>○ ≥ 0.1 % by mass</li></ul> <p>_____ %(w/w)</p>



## Annex 4:

### LIST OF PARTICIPANTS

country	name	e-mail	Phone/Fax	Department/address
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## Annex 5:

### INTERPRETATION OF TERMS IN DIRECTIVE 2003/3/EC

Appendixes to the “azodyecolourant” Directive 2002/61/EC (19<sup>th</sup> Amendment of Dir. 76/769/EEC) and “blue colourant” Directive 2003/3/EC (12<sup>th</sup> adaptation to technical progress of Dir. 76/769/EEC) contains a non exhaustive list of textile and leather goods which may come into direct and prolonged contact with human skin or oral cavity cf: the prohibition in Annex 1 to Restrictions Directive 76/769/ECC, point 43. As the list is not exhaustive it is, in the cases where products are not mentioned, necessary to make interpretations using comparable products from the list in order to decide whether the products are included or not. An example of this is quilts, taken from the list below. Bed linen and sleeping bags are on the list but duvets are not. As quilts are generally used without covers, they are assessed to be covered by the prohibition.

The formulation “direct and prolonged contact with skin or oral cavity “ is a relatively loose formulation. An example would be the use of a potholder which is usually of short duration but it is always used directly in contact with skin, only in very rare cases would one wear another glove under the potholder or oven glove. There is no unambiguous list of answers, but manufacturers should keep in mind that the list in the Appendix is not exhaustive and that the concept of time may be “elastic”.

The following comments have been made in connection with enquiries about products which are not mentioned in the Appendix.

Aprons	Yes, if there is contact with the skin i.e. via a strap around the neck. No, aprons without bibs are not in contact with skin.
Potholders	Yes, there is contact with skin.
Bags for cosmetics or toiletries	Rarely, but consideration has been given to whether children might play with the products.
Bags	Yes, leather handbags are on the list and there is contact with skin.
Quilts	Yes, as with sleeping bags – the list is not exhaustive.
Oven Gloves	Yes, there is direct contact with skin.
Chair cushions	Yes, as with chair covers, the list is not exhaustive.
Placemats	No, table napkins, Yes
Bath mats	Yes, there is contact when walked on in bare feet.
Pouf	Yes, as with chair covers, the list is not exhaustive.